

## Abstracts

A257

Child-Friendly version of EQ-5D will be discussed to realize the final version of the questionnaire.

PIH15

#### DEVELOPMENT OF AN ICIQ NOCTURNAL ENURESIS QOL QUESTIONNAIRE

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**OBJECTIVES:** There is a lack of a validated QoL questionnaire assessing the psychological burden and treatment benefits of bed-wetting as evaluated by the child. This abstract reports the results of the initial validation tests for such a questionnaire. It is being developed in accordance with the validation standards of the ICIQ. **METHODS:** A literature review was conducted and led to quantitative interviews with 28 children suffering from Nocturnal Enuresis and 28 pairs of parents. Consequently a questionnaire including 20 questions was developed and tested in a multinational Randomised Clinical Trial completed by 196 children and 196 parents in antidiuretic treatment before and during the trial. **RESULTS:** Based on review and interviews, a list of issues was identified: Social isolation, emotional distress, low self-esteem, problems in parent-child relation, delayed independence and fear of being teased at school and home. Two or more questions were developed for each of the six issues to add room for elimination of poorly performing questions. The RCT data indicated promising cluster effect, i.e. the well treated children showed a high QoL, and the questions seemed test-retest consistent. Some questions yield a high level of missing answers. **CONCLUSION:** The tests led to reformulation of the questions yielding missing answers and the questionnaire is now ready for the coming validation, including sensitivity analysis and item reduction. We are convinced that future research in Nocturnal Enuresis will profit from the final questionnaire.

PIH16

#### TREATMENT DURATION FOR ATROPHIC VAGINITIS: CLINICAL TRIALS VERSUS "THE REAL WORLD"

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**OBJECTIVE:** Duration of vaginal estrogen therapy (VET) may vary. This study sought to compare and contrast treatment duration of women prescribed vaginal tablets (VT) or vaginal creams (VC) in clinical trials with that in clinical practice. **METHODS:** Adults initiating VET between January and June, 2004 in 57 managed care plans (PharMetrics database) in the United States were identified and followed for up to 10 months to examine their treatment duration. A Kaplan-Meier analysis was performed to obtain average and median time to discontinuation for individuals treated with VT or VC. A weighted average of treatment duration was calculated for a total of seven clinical trials identified in the literature. These results were stratified by study inclusion criteria. Differences in average treatment duration were statistically tested using t-tests. **RESULTS:** Of 5599 patients undergoing VET (mean age = 54 ± 9.1 years), 4355 (77.8%) received VC and 1244 (22.2%) received VT. Patients prescribed VT had a significantly longer average (median) treatment compared to patients prescribed VC [(198.5 ± 82.4 days (221 days) vs. 177.1 ± 86.7 days (190 days)); p < 0.01]. This duration in clinical practice was significantly longer than that in seven clinical trials [165 days (240 days for three trials of both

VC and VT; 90 days for two VT-only studies; and 69 days for two VC-only studies)]. **CONCLUSIONS:** Duration of VET was longer in a real-world clinical practice setting than in clinical trials. Moreover, subjects treated with VT exhibited significantly longer treatment duration than subjects treated with VC. Possible factors explaining longer duration with VT include ease of use, reduced messiness, accurate dosing resulting in improved effectiveness and fewer adverse events, and consequently improved quality of life. Future studies should prospectively examine factors associated with these differences.

PIH17

#### ASSESSING PSYCHOLOGICAL BURDEN AND TREATMENT BENEFITS IN PEDIATRIC PATIENTS WITH BEDWETTING

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**OBJECTIVES:** Nocturnal enuresis (NE) can pose significant psychological burden on children's self-esteem and quality of life (QoL). Therefore, patient-reported outcome (PRO) measurement is essential to fully understand the burden posed by NE and the benefits of treating this condition. To our knowledge, it has not been investigated which instruments should be used to assess the psychological burden of NE. The aim of this study was to identify and evaluate PRO instruments used in children with NE. **METHODS:** A literature search of Medline and other databases was conducted to identify publications from 1995–2006 which contained PRO instruments used in children with NE. **RESULTS:** 40 studies and 32 PRO instruments were identified. Instruments were evaluated based on psychometric properties and responsiveness to change. Some studies used several PRO instruments. The Child Behavior Checklist was the most commonly used instrument (8/40 studies, 20%). Measures of self-esteem were used in 11/40 studies (28%). No generic QoL measures were used in these trials. No disease-specific PRO instruments were found to be fully validated in the NE population. Currently, a new disease-specific QoL questionnaire is in development for NE. **CONCLUSIONS:** The results of this study highlight the lack of patient-reported disease-specific PRO measures to assess the burden and treatment benefits of NE. A new disease-specific instrument may be able to fill this gap.

PIH18

#### DIMENSIONS OF HRQOL AND SATISFACTION WITH LIFE IMPROVE IN ED PATIENTS SWITCHING FROM OTHER ORAL ED MEDICATION TO TADALAFIL

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**OBJECTIVES:** To compare Finnish patients with erectile dysfunction (ED) and men from the Finnish general population in measures of self-reported Health-Related QOL (HRQoL) and satisfaction with life, and to investigate whether switching patients from current oral ED medication to tadalafil impacts these measures. **METHODS:** A total of 202 Finnish men over 18 years successfully treated with oral ED prescription medication (tadalafil excluded) voluntarily entered this multicenter, open-label, one-arm, 3-month study. Upon enrollment, patients discontinued their previous therapy and were started on tadalafil 10 or 20 mg (dose determined by investigator) on demand. Outcome was measured using the 15D and Life Satisfaction-11 (LiSat-11) checklists. 15D is a generic, comprehensive, 15-dimensional, standardized, self-administered measure of HRQoL